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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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YOUNG & THOMPSON
209 Madison Street
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Alexandria, VA 22314

EXAMINER

NEWMAN, MICHAEL A

ART UNIT	PAPER NUMBER
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2624

NOTIFICATION DATE	DELIVERY MODE
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09/29/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/571,789	Applicant(s) SELSE ET AL.	
	Examiner MICHAEL A. NEWMAN	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/15/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The preliminary amendment filed on March 15th, 2006 has been entered.
2. In view of the amendment to the claims, the cancellation of claims 1 – 30 and the addition of claims 31 – 58 have been acknowledged.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows (see also MPEP 2106):

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

The USPTO "Examination of Patent Applications for Patent Subject Matter Eligibility of Computer Readable Media" (Official Gazette notice of 23 February 2010 - 1351 OG 212), reads as follows (see also MPEP 2106):

The United States Patent and Trademark Office (USPTO) is obliged to give claims their broadest reasonable interpretation consistent with the specification during proceedings before the USPTO. See *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989) (during patent examination the pending claims must be interpreted as broadly as their terms reasonably allow). The broadest reasonable interpretation of a claim drawn to a computer readable medium (also called machine readable medium and other such

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variations) typically covers forms of non-transitory tangible media and transitory propagating signals per se in view of the ordinary and customary meaning of computer readable media, particularly when the specification is silent. See MPEP 2111.01. When the broadest reasonable interpretation of a claim covers a signal per se, the claim must be rejected under 35 U.S.C. § 101 as covering non-statutory subject matter. See *In re Nuijten*, 500 F.3d 1346, 1356-57 (Fed. Cir. 2007) (transitory embodiments are not directed to statutory subject matter) and Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101, Aug. 24, 2009; p. 2.

The USPTO recognizes that applicants may have claims directed to computer readable media that cover signals per se, which the USPTO must reject under 35 U.S.C. § 101 as covering both non-statutory subject matter and statutory subject matter. In an effort to assist the patent community in overcoming a rejection or potential rejection under 35 U.S.C. § 101 in this situation, the USPTO suggests the following approach. A claim drawn to such a computer readable medium that covers both transitory and non-transitory embodiments may be amended to narrow the claim to cover only statutory embodiments to avoid a rejection under 35 U.S.C. § 101 by adding the limitation "non-transitory" to the claim. Cf. *Animals - Patentability*, 1077 Off. Gaz. Pat. Office 24 (April 21, 1987) (suggesting that applicants add the limitation "non-human" to a claim covering a multi-cellular organism to avoid a rejection under 35 U.S.C. § 101). Such an amendment would typically not raise the issue of new matter, even when the specification is silent because the broadest reasonable interpretation relies on the ordinary and customary meaning that includes signals per se. The limited situations in which such an amendment could raise issues of new matter occur, for example, when the specification does not support a non-transitory embodiment because a signal per se is the only viable embodiment such that the amended claim is impermissibly broadened beyond the supporting disclosure. See, e.g., *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998).

4. Claims 52 – 58 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claims 52 – 58 define a computer program product embodying functional descriptive material (i.e., a computer program or computer executable code). However, the claim does not define a “non-transitory computer-readable medium or non-transitory computer-readable memory” and is thus non-statutory for that reason (i.e., “When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized” – Guidelines Annex IV). The scope of the presently claimed invention encompasses products that are not necessarily computer readable, and thus NOT able to impart any functionality of the recited program. The examiner suggests amending the claim(s) to embody the program on

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“non-transitory computer-readable medium” or equivalent; so as to explicitly exclude the interpretation of the computer readable medium as a “signal”, “carrier wave”, or “transmission medium” which are deemed non-statutory (refer to “note” below). Any amendment to the claim should be commensurate with its corresponding disclosure.

Note:

“A transitory, propagating signal ... is not a “process, machine, manufacture, or composition of matter.” Those four categories define the explicit scope and reach of subject matter patentable under 35 U.S.C. § 101; thus, such a signal cannot be patentable subject matter.” (In re Nuijten, 84 USPQ2d 1495 (Fed. Cir. 2007)). Should the full scope of the claim as properly read in light of the disclosure encompass non-statutory subject matter such as a “signal”, the claim as a whole would be non-statutory.

Merely reciting functional descriptive material as residing on a “tangible” or other medium is not sufficient. If the scope of the claimed medium covers media other than “non-transitory computer readable” media (e.g., “a tangible media”, a “machine-readable media”, etc.), the claim remains non-statutory. The full scope of the claimed media (regardless of what words applicant chooses) should not fall outside that of a non-transitory computer readable medium.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 31 – 38, 41 – 49, 51 – 56 and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Marshall et al. (U.S. Patent No. 7,298,876). Hereinafter referred to as Marshall.

a. Regarding claims 31, 41, 42, 48, 49, 50, 52 and 58, Marshall teaches a digital mammography system and method comprising: means for generating at least one digital mammographic image of a patient (**Col. 2 lines 30 – 40**); means for computerized processing of at least one digital mammographic image to identify landmark areas of the breast (**Col. 5 lines 28 – 37 and Col. 6 lines 63 – 67**) [**Note that the pectoral muscle is clearly a landmark area used in mammographic screening**], characterized in that said system further comprises: means for computerized processing based on image processing measurements on identified landmark areas of the breast together with at least one associated criterion for assessing image positioning quality to produce an automated real-time positioning quality assessment result (**Col. 6 lines 6 lines 63 – 67 and Col. 10 lines 62 – 67**) [**Note that proper placement is**

automatically calculated by the system based on the identified pectoral muscle]; means for determining, based on the positioning quality assessment result, whether the image positioning quality of said at least one mammographic image is sufficient **(Col. 6 line 62 to Col. 7 line 7 and Col. 10 lines 62 – 67)**

[Note that the proper placement is compared to a minimum required standard]; means for communicating said positioning quality assessment result on a user interface to enable a real-time decision by a technologist whether to retake said at least one mammographic image with improved positioning **(Col. 5 line 65 – Col. 6 line 7) [Note that user is alerted as to whether the image needs to be retaken].**

- Regarding claims 52 and 58, Marshall further teaches implementing the above functionality on a computer system by embodying the method steps on a computer readable medium as computer program instructions **(Col. 4 lines 6 – 21 and lines 50 – 52).**

b. Regarding claims 32, 43, 51 and 53, Marshall teaches the method, systems and program according to claims 31, 42, 49 and 52, wherein said at least one criterion for assessing image positioning quality includes a set of threshold values **(Col. 5 lines 65 – 67).**

c. Regarding claims 33 and 44, Marshall teaches the method and system according to claims 31 and 42, further comprising the step of retaking said at least one mammographic image with improved positioning if the quality assessment result indicates that the image is inadequately positioned **(Col. 6**

lines 62 – 67 and Col. 11 lines 32 – 33) [Note that the user would clearly attempt to reposition the patient to ‘an improved’ position].

d. Regarding claims 34 and 45, Marshall teaches the method and system according to claims 33 and 44, comprising multiple retakes of inadequately positioned images, continuously updating which image or set of images among said multiple retakes that is considered most adequate **(Col. 49 – 64 and Col. 6 lines 15 – 21) [Note that the multiple retakes are stored for logging and the trend analysis logic uses past and current results to determine whether there are negative or positive trends by determining whether older or newer images are more adequate (i.e. increase or decreasing deviations). Marshall teaches that by continually updating the trend analysis, problems are caught immediately].**

e. Regarding claims 35, 46 and 54, Marshall teaches the method, system and program according to claims 31, 42 and 52, wherein said positioning quality assessment result further comprises visual indication of inadequately positioned areas of the breast on a graphical user interface **(Col. 5 lines 7 – 13, Col. 6 lines 1 – 7 and lines 62 – 67) [Note that a visual alert is issued through the user interface when the image needs to be retaken because characteristic pectoral muscle areas are positioned incorrectly].**

f. Regarding claims 36, 38, 47, 55, Marshall teaches the method, system and program according to claims 31, 42 and 52, wherein said positioning quality assessment includes a number of user-configurable parameters and thresholds

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between good and bad positioning, thus allowing a selectable level of detail in communicating the result **(Col. 10 line 55 to Col. 11 line 5 and Col. 11 line 58 to Col. 12 line 15) [Note that the thresholds and alerts are user selectable and configurable].**

g. Regarding claim 37, Marshall teaches the method according to claim 31, wherein said positioning quality assessment result includes at least one of a visual part and a statistics part **(Col. 5 lines 49 to Col. 6 line 32) [Note that the system generates both visual/auditory alerts as well as historical/trend analysis reports].**

h. Regarding claim 56, Marshall teaches the computer program product according to claim 52, wherein said computer program product is implemented in an image acquisition workstation of a digital mammography system **(Col. 4 lines 6 – 67, Col. 3 lines 55 – 58 and Col. 2 lines 3 – 8) [Note that the computer system is part of the mammography computer-aided diagnosis system].**

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall et al. (U.S. Patent No. 7,298,876). Hereinafter referred to as Marshall.

a. Regarding claim 57, Marshall teaches all the limitations of the dependent claim 56, as set forth in the 35 U.S.C. 103 rejection of claim 56 above. As discussed above, Marshall teaches implementing the quality assessment functionality on a computer system, which is part of a computer-aided diagnosis system, by embodying on a computer readable medium the appropriate software instructions. Marshall; however, **does not explicitly** teach that the program is implemented for integrated operation with existing software in said workstation. Initially, it is noted that Marshall clearly teaches that the computer system is to be used with existing computer-aided diagnosis systems, which have existing software. Official Notice is taken that it is old and well known in the art that computer systems require some form of operating system software to handle and distribute limited hardware resources amongst the various processes and programs being executed on the computer system. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

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to design the computer software instructions, used to implement the functionality taught by Marshall, to integrate into the existing computer's operating system software, in order to ensure that the software would be compatible with the operating system and would be executable by the computer system's hardware to impart its functionality.

10. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall et al. (U.S. Patent No. 7,298,876) in view of Hartman et al. (U.S. Patent No. 7,146,031). Hereinafter referred to as Marshall and Hartman, respectively.

a. Regarding claims 39 and 40, Marshall teaches all the limitations of the independent claim 31, as set forth in the 35 U.S.C. 102 rejection of claim 31 above. Marshall teaches determining the positioning quality of a mammography image captured by a computer aided diagnosis system. However, Marshall **does not teach** wherein said at least one mammographic examination comprises several projections, being at least a CC (Cranio-caudal) projection, an MLO (Medio-lateral oblique) projection, an LM (Latero-medial) projection and an ML (Medio-lateral) projection. **Pertaining to the same field of endeavor, Hartman teaches a computer-aided diagnosis system for detection of abnormalities on mammographic images (Hartman Col. 3 line 61 to Col. 4 line 4). Specifically, Hartman teaches that the CAD system can display multiple views of the same breast, such that if the attention of the radiologist is drawn to specific areas of a first image, the area can be compared to**

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corresponding areas of other views (Hartman Col. 4 lines 50 – 61). Hartman further teaches that in the United States, it is common for each mammography study to be composed of an image of the top view (Cranial Caudal) and a lateral view (Medio-Lateral Oblique) (Hartman Col. 5 lines 55 – 63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Marshall's system to evaluate the positioning of mammography images, which as taught by Hartman, commonly show at least the Cranial Caudal and Medio-Lateral Oblique views, in order to ensure all the mammographic views useful to the diagnosis are properly obtained.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Karssemeijer et al. (U.S. Patent No. 7,203,348) teaches applying automatic thickness correction to mammogram images in a CAD system.
- b. Kagermeier et al. (U.S. Patent No. 7,343,189) teaches a system allows repeatability in patient positioning for medical imaging.
- c. Abdel –Mottaleb (U.S. Patent No. 5,579,360) teaches computer analysis of mammogram images in which detection is carried out using views from different directions.

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d. Vafai (U.S. Patent No. 5,825,910) teaches processing a mammogram to detect contour and extract boundaries.

e. "Digital Mammography Features Assure Proper Breast Positioning."

DiagnosticImaging.com - UBMMedica (2002): 1-2. Web. 24 Sep 2010.

<http://www.diagnosticimaging.com/breast/content/article/113619/1211792>.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL A. NEWMAN whose telephone number is (571)270-3016. The examiner can normally be reached on Mon - Thurs from 9:30am to 6:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh M. Mehta can be reached on (571) 272-7453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhavesh M Mehta/
Supervisory Patent Examiner, Art Unit 2624

M.A.N.